



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0797]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing State enforcement notifications.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Denver Presley, II,
Office of Information Management,
Food and Drug Administration,
1350 Piccard Dr.,
PI50-400B,
Rockville, MD 20850,
301-796-3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

State Enforcement Notifications--21 CFR 100.2(d) (OMB Control Number 0910-0275)--

Extension

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the FD&C Act in their own names but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2 (d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the FD&C Act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden ¹					
21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
100.2(d)	1	1	1	10	10

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any new enforcement notifications; therefore, the Agency estimates that one or fewer notifications will be

submitted annually. Although FDA has not received any new enforcement notifications in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: November 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-29058 Filed 11/08/2011 at 8:45 am; Publication Date: 11/09/2011]